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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,193	11/29/2000	Chih-Ming Chen	300.1023	6199
23280	7590	10/06/2004	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,193

Applicant(s)

CHENG ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8-20,24-33 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8-20,24-33 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 07/06/04. Claims 1, 3, 4, 6, 8-20, 24-33 and 35-39 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to the claims.

Claim Objections

2. The objection to claims 2, 7 and 34 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the cancellation of the claims 2, 7 and 34.

Claim Rejections - 35 USC § 102

3. Claims 1, 3, 4, 6, 8-20 and 24-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Scott (US 3,621,097).

Applicants argue:

a. "Examiner's failure to consider certain limitations of the claims (which the examiner refers to as 'intended use' of formulations) is improper. The Examiner is reminded that "[t]here is nothing inherently wrong with defining some part of an invention in functional terms," and that "functional language does not, in and itself, render a claim improper." MPEP 2173.059(g) (citing *In re Swinehart*, 169 USPQ 226 (CCPA 1971)). In addition "[a] functional limitation must be evaluated and considered,

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just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” MPEP 2173 05(g).”

Applicants then state that the Examiner must consider the limitation of claim 1.

b. Secondly, applicants, while acknowledging that Scott discloses sustained release tablets, argue that Scott does not teach that the formulation provides therapeutic plasma levels of said metformin to a human patient over 24 hours period as recited in claim 1 and that Scott fails to teach “said formulation providing an AUC which is increased by the presence of food as compared with administration in the fasting state” according to the recitation of claims 1, 6, 9, 12, 15, 18, 24 and 27. Applicants further argue that Scott fails to teach that “therapeutic levels of said metformin are attained in said human for 12 to 24 hours, and said dosage does form does not exhibit a decrease in the bioavailability of metformin if taken with food” according to the recitation of claim 31.

c. Scott does not disclose a 24-hour therapeutic plasma levels of metformin because Scott does not provide directions on how to make controlled release metformin formulation and that Examiner’s position is incorrect regarding the interpretation that the influence of food on the bioavailability of the metformin is a property of the metformin formulation and applicants support this assertion by referencing the 52nd Edition of the Physician’s Desk Reference (1998), immediate release metformin product, GLUCOPHAGE.

4. Applicants’ arguments filed 07/06/04 have been fully considered but they are not persuasive.

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Regarding the issue of a, it is respectfully noted that in the case cited by applicants, the issue was rejection under 35 USC 112. The present rejection has to do with inherent properties and functions derived from the inherent properties of the metformin formulation. Specifically, one of the opinions in the Swinehart case is "mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; additionally, where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be an inherent characteristic of prior art, it possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on." Specifically, metformin formulation is claimed in the instant application and the prior art discloses metformin formulation. What makes the instant metformin exhibit the property recited in the instant claims and what would make the prior art metformin formulation to have properties that differ from the same metformin of the instant claims? Applicants have not shown structural and compositional differences between the claimed metformin formulation and the disclosed metformin formulation. Why must the instant formulation have the recited properties and the formulation of the prior art not? What is the difference between the two metformin formulations? Applicants have not shown the difference between the two. Examiner considered the characteristic/function/property of the formulation, hence the determination of inherency. The functional limitation was evaluated and found to be inherent to a broad metformin formulation of the prior art and applicants have not provided the difference between the instant metformin and the metformin of the prior art. Applicants have not proved that the

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metformin formulation disclosed by the prior art does not possess the characteristic/property/function.

Regarding b, the issue is the same, inherent characteristic/property/function. There is no demonstration by applicants that the metformin of the prior art does not possess characteristic relied on. Examiner continues to take the position that when the metformin of the prior art is administered, it would provide the responses recited in the instant claims. It is respectfully noted that applicants broadly claim metformin formulation without specifically claiming any amounts or structure that shows a difference from the prior art.

Regarding c, applicants have not claimed method of formation or preparation of metformin formulation and thus applicants are relying on limitations that are not claimed. Regarding the PDR reference, for which applicants quote that food lowers the absorption of metformin by 40% and therefore, Examiners analysis about the influence of food is in error. It is respectfully noted that applicants in that assertion refers that a single 850 mg tablet of metformin administered with food or in a fasting state. Again in the instant claims no specific dose is administered or the formulation claimed is a broad metformin formulation. There is no proof provided by applicants that the characteristics of the instant broad metformin formulation differs from the disclosed metformin formulation that is the same as that, which is claimed.

5. Claims 1, 3, 4, 6, 8-20 and 24-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (US 5,055,306).

Applicants remind the Examiner that functional limitations must be considered and that Barry fails in the very least to teach the functional limitations recited in claims 1, 6, 8, 9, 12, 15, 18, 24 and 27 and 31.

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6. Applicants' arguments filed 07/06/04 have been fully considered but they are not persuasive.

The same explanation on applicants' position regarding the functional language and claim 31 will be given here as was given above for applicants' argument on Scott. Examiner evaluated the functional language recited in the claims and found that the function of the instant metformin formulation is inherent to the metformin formulation of the prior art and applicants provided no demonstration to show that the metformin formulation of the prior art would not possess the recited function/property/characteristic of the instant metformin formulation. And in the Swinehart case referred to by applicants, it is respectfully noted that the opinion reads, "mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; additionally, where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be an inherent characteristic of prior art, it possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on." Applicants provide no prove to show differences between the claimed metformin formulation and the disclosed metformin formulation.

In summary, it appears that applicants' metformin formulation differs from the disclosed metformin formulation and applicants have not yet claimed that difference, provided the difference or claimed the metformin formulation that is applicants' invention. The metformin formulation claimed by applicants reads on the metformin formulation of the prior art. And function or property or characteristic inherent to the broad metformin formulation does not distinguish the claimed metformin formulation from the prior art. Applicants are respectfully

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encouraged to provide any structural and/or compositional differences between the claimed and disclosed and also provide prove that the formulations of the prior art differ form the instant broad metformin formulation.

Claim Rejections - 35 USC § 103

7. Claims 33 and 35-39 remain under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 5,055,306).

Applicants argue that Barry fails to teach orally administering metformin formulation on a once a day basis to a diabetic patient in the presence of food or in fasting conditions so that a decrease in the bioavailability of metformin is not exhibited.

8. Applicants' arguments filed 07/06/04 have been fully considered but they are not persuasive.

This obviousness rejection is on the premise that it would be within the purview of the person of ordinary skill or the skilled artisan to ascertain the ideal times for administering the formulation, that is with food or in fasting state and the rejection is not anticipatory.

Thus the burden is on applicants to provide a proof to demonstrate the difference between the instant metformin and the metformin of the prior art or to show that the metformin of the prior art would not possess the inherent recited characteristics/property/function.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after


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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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